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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 9706.204-2022

**Medical electrical equipment - Part 2-4: Particular requirements
for the basic safety and essential performance of cardiac
defibrillators**

医用电气设备 第2-4部分：心脏除颤器的基本安全和基本性能专用要求

(English Translation)

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Introduction

201.1 Scope, Purpose and Related Standards

foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1. Structure and Drafting Rules of Standardization Documents" drafted.

This document is part 2-4 of GB 9706 "Medical Electrical Equipment". GB 9706 has released the following parts.

- Part 1. General requirements for basic safety and basic performance;
- Part 1-3. General Requirements for Basic Safety and Essential Performance Collateral Standard. Radiation Protection of Diagnostic X-ray Equipment;
- Part 2-1. Specific requirements for basic safety and basic performance of electron accelerators with energies from 1MeV to 50MeV;
- Part 2-2. Special requirements for basic safety and basic performance of high-frequency surgical equipment and high-frequency accessories;
- Part 2-3. Specific requirements for basic safety and basic performance of shortwave therapy equipment;
- Part 2-4. Particular requirements for basic safety and basic performance of cardiac defibrillators;
- Part 2-5. Specific requirements for the basic safety and basic performance of ultrasonic physiotherapy equipment;
- Part 2-6. Specific requirements for basic safety and basic performance of microwave therapy equipment;
- Part 2-8. Particular requirements for basic safety and basic performance of therapeutic X-ray equipment with energy from 10kV to 1MV;
- Part 2-11. Particular requirements for basic safety and basic performance of gamma beam therapy equipment;
- Part 2-12. Specific requirements for basic safety and basic performance of critical care

ventilators;

--- Part 2-13.Particular requirements for basic safety and basic performance of anesthesia workstations;

--- Part 2-16.Particular requirements for basic safety and basic performance of hemodialysis, hemodiafiltration and hemofiltration equipment;

--- Part 2-17.Special requirements for the basic safety and basic performance of automatically controlled brachytherapy afterloading equipment;

--- Part 2-18.Particular requirements for basic safety and basic performance of endoscopic equipment;

--- Part 2-19.Specific requirements for the basic safety and basic performance of infant incubators;

--- Part 2-24.Particular requirements for basic safety and basic performance of infusion pumps and infusion controllers;

--- Part 2-25.Particular requirements for basic safety and basic performance of electrocardiographs;

--- Part 2-26.Specific requirements for basic safety and basic performance of EEG machines;

--- Part 2-27.Particular requirements for basic safety and basic performance of ECG monitoring equipment;

--- Part 2-28.Particular requirements for basic safety and basic performance of medical diagnostic X-ray tube assemblies;

--- Part 2-29.Specific requirements for basic safety and basic performance of radiotherapy simulators;

--- Part 2-36.Particular requirements for the basic safety and basic performance of in vitro induced lithotripsy equipment;

--- Part 2-37.Particular requirements for basic safety and basic performance of ultrasonic diagnostic and monitoring equipment;

--- Part 2-39.Particular requirements for basic safety and basic performance of peritoneal dialysis equipment;

--- Part 2-43.Particular requirements for basic safety and basic performance of interventional X-ray equipment;

--- Part 2-44.Particular requirements for the basic safety and basic performance of X-ray computed tomography equipment;

--- Part 2-45.Mammography equipment and mammography stereotaxic devices for basic safety and basic performance specific

Require;

--- Part 2-54.Particular requirements for the basic safety and basic performance of X-ray photography and fluoroscopy equipment;

--- Part 2-60.Particular requirements for basic safety and basic performance of dental equipment;

--- Part 2-63.Special requirements for basic safety and basic performance of dental X-ray machines for extraoral imaging;

--- Part 2-65.Special requirements for basic safety and basic performance of intraoral imaging dental X-ray machines.

This document replaces GB 9706.8-2009 "Medical Electrical Equipment Part 2-4.Special Requirements for the Safety of Cardiac Defibrillators", and

Compared with GB 9706.8-2009, in addition to structural adjustment and editorial changes, the main technical changes are as follows.

--- Added basic performance requirements (201.4.3);

--- Added requirements for defibrillator electrodes (201.7.2.103);

--- Added requirements for external pacing (201.109);

--- Changed some test methods and test circuits.

This document is modified to adopt IEC 60601-2-4:2018 "Medical Electrical Equipment Part 2-4.Basic Safety and Fundamentals of Cardiac Defibrillators

Capability-Specific Requirements".

The technical differences between this document and IEC 60601-2-4:2018 and their reasons are as follows.

--- Regarding normative reference documents, this document has made adjustments with technical differences to adapt to the technical conditions of our country and the adjustment situation

Centrally reflected in.201.2 "Normative Reference Documents", the specific adjustments are as follows.

- Replace CISPR11 with GB 4824-2019 which is equivalent to adopting international standards;

- Replacing IEC 60601-1:2005/AMD1:2012 with GB 9706.1-2020 which is modified to adopt international standards;

- Replace IEC 61000-4-2 with GB/T 17626.2 which is equivalent to adopting international standards;
- Replace IEC 61000-4-3 with GB/T 17626.3 which is equivalent to adopting international standards;
- Replace IEC 61000-4-4 with GB/T 17626.4 which is equivalent to adopting international standards;
- Replace IEC 61000-4-5 with GB/T 17626.5-2019 which is equivalent to adopting international standards;
- Replace IEC 61000-4-8 with GB/T 17626.8 which is equivalent to adopting international standards;
- Replace ISO 15223-1:2016 with YY/T 0466.1-2016 which is equivalent to adopting international standards;
- Replacing IEC 60601-1-2:2014 with YY9706.102-2021 which has been modified to adopt the international standard.
- Delete the third paragraph in 201.102.3.1, because the content of the third paragraph and the fifth paragraph in the original text are repeated.
- Changed Figure 201.106, adding a metal plate between the electrode and the sponge.
- 201.108.1.11 The conversion unit "pound" (4lb) has been deleted.

The following editorial changes have been made to this document.

- The column item symbols in 201.106 are numbered sequentially, and the column items a), b) and c) appearing for the second time in the original text are changed to c), d) and e); in the corresponding penultimate paragraph "b) and c)" are changed to "c) and d)";
- Removed the column item symbol "d)" in 201.107;
- 201.109.7 added a note stating "ppm";
- In 201.108.105, ISO 10993 (all parts) for informative references was replaced with "standards related to biocompatibility";
- Replaced IEC 60529 with GB/T 4208-2017 cited for information;
- Replace ANSI/AAMIEC 12.2000 with YY/T 0196-2005 and YY1079-2008 cited for information and ANSI/AAMIEC 13.2002;
- Removed the term index at the end of the text.